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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,214	03/29/2004	Lasse Wesseltoft Mogensen	8465/43	5131

7590 02/27/2007  
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EXAMINER
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MACNEILL, ELIZABETH

ART UNIT	PAPER NUMBER
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3767

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/27/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/813,214

Applicant(s)

MOGENSEN ET AL.

Examiner

Elizabeth R. MacNeill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 July 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 50-96 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 50-59 and 65-96 is/are rejected.
- 7) ☒ Claim(s) 60-64 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date See Continuation Sheet.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :6/18/04; 6/13/05; 7/13/05; 3/13/06; 4/17/06.

## **DETAILED ACTION**

### ***Claim Objections***

1. Claims 54 and 55 are objected to because of the following informalities: Claim 54 depends from cancelled claim 2. Based on antecedent basis in the claims, it appears claim 54 should depend from claim 51. For the purposes of examination, claim 54 will be treated as depending from claim 51. Appropriate correction is required.
2. Claims 62 and 75 are objected to because of the following informalities: "being essentially plane" should read, "being essentially planar". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 50-57, 59, 65-68, 72-85, 89, and 93-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Funderbunk et al (US 6,093,172) in view of Turner et al (US 4,817,603).

Funderbunk teaches an injector assembly comprising a sterile insertion set with a housing (20), tubing (22) and a hollow cannula (26), a device housing (28), a plunger (30), with flexible plastics members (56) with insertion needle (12) and support structure (144), and a spring (36) with a trigger (138) and lock (78). Funderbunk does not disclose a cover over the forward end of the housing.

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Turner discloses a spring loaded needle with a plunger and housing (Fig 1) where the forward end of the housing is covered with a removable cap (14) which is sealed to the housing prior to use.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a sealing cap on the device of Funderbunk in order to prevent the insertion needle or cannula from being contaminated prior to use.

Regarding claims 53,79 Funderbunk discloses inserting a glucose sensor (Col 1 line 27)

5. Claims 50-59, 65-88, and 90-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Funderbunk et al (US 6,093,172) in view of Karakashian (US 3,937,219)

Funderbunk teaches an injector assembly comprising a sterile insertion set with a housing (20), tubing (22) and a hollow cannula (26), a device housing (28), a plunger (30), with flexible plastics members (56) with insertion needle (12) and support structure (144), and a spring (36) with a trigger (138) and lock (78). Funderbunk does not disclose a cover over the forward end of the housing.

Karakashian discloses an injection assembly (4) sealed with a sterile cover (1) which has a membrane and allows for flow-through sterilization (Fig 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a sterile cover on the device of Funderbunk in order to prevent the insertion needle or cannula from being contaminated prior to use.

Regarding claims 53,79 Funderbunk discloses inserting a glucose sensor (Col 1 line 27)

Regarding claim 58, it would have been obvious to one of ordinary skill in the art to include the shelf life of the assembly on the sterile packaging for safety purposes.

***Allowable Subject Matter***

6. Claims 60-64 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach or suggest the use of a spring member comprising a number of individual, flexible plastics strips extending around a respective part of the periphery of the plunger, in combination with the other elements of the claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 7:00-3:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM

*Clizeta*  
*Mark*  
*2/6/07*

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

*Kevin C. Sirmons*